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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,908	08/01/2005	Bernd Kuhn	Le A 36 031	7332

35969 7590 09/25/2007

JEFFREY M. GREENMAN
BAYER PHARMACEUTICALS CORPORATION
400 MORGAN LANE
WEST HAVEN, CT 06516

EXAMINER	
MAIER, LEIGH C	

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
09/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,908	KUHN ET AL.	
	Examiner	Art Unit	
	Leigh C. Maier	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/8/04, 2/13/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Mauler et al (J. Pharmacol. Exp. Ther., 2002 – Published online June 13, 2002. Mailed June 14, 2002).

Mauler teaches a composition comprising 1% BAY 38-7271 (compound I) and a cyclodextrin. See paragraph bridging the columns of page 362. The composition is suitable for continuous infusion. This composition is prepared by dissolving BAY 38-7271 in ethanol and adding a 10% solution of cyclodextrin. The reference is silent regarding the solvent of the cyclodextrin. However, for a physiological solution, if the solvent is not named, it would be expected to be water.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mauler et al (J. Pharmacol. Exp. Ther., 2002) in view of Szabo et al (J. Pharmacol. Exp. Ther., 2001).

Mauler teaches as set forth above. The reference further teaches that BAY 38-7271 is a cannabinoid receptor agonist with a variety of therapeutic uses. See 1st paragraph at page 359. The compound is deemed similar in activity to other known agonists, such as WIN 55,212-2 and CP 55,940.

As discussed above, one of ordinary skill would expect that the cyclodextrin solvent would be water. However, it may be that this is not the case.

Szabo teaches that an aqueous solution comprising a cyclodextrin is a suitable vehicle for infusing the cannabinoid agonists, WIN 55,212-2 and CP 55,940. See page 820, 2nd paragraph under "Drugs." The reference further notes that other drugs are dissolved in ethanol and saline.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare a composition comprising BAY 38-7271 for infusion using any

suitable physiologically solution for administration as taught by Mauler. One of ordinary skill would use a vehicle known to be used for other similar therapeutic compounds, such as the aqueous solution comprising a cyclodextrin, with a reasonable expectation of success. In the absence of unexpected results, it would be further within the scope of the artisan to modify this vehicle with other standard physiological solvents, such as ethanol and/or saline to optimize the characteristics of the composition through routine experimentation. It would be further within the scope of the artisan to optimize the amounts of compound I, cyclodextrin and ethanol in said composition for the intended use.

The instant claims recite a composition comprising compound I and various standard physiological excipients. However, the examiner does not find there to be any evidence of criticality in any particular mix of components.

Claims 1- 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mauler et al (J. Pharmacol. Exp. Ther., 2002) in view of Szabo et al (J. Pharmacol. Exp. Ther., 2001) and Nakazi et al (Naunyn-Schmiedeberg's Arch. Pharmacol., 2000).

Mauler and Szabo teach as set forth above. The references are silent regarding the pH of the solutions or the use of citric acid.

Nakazi teaches that a citrate buffer (pH 4.8) is a suitable vehicle for cerebral infusion of the cannabinoid agonists, WIN 55,212-2 and CP 55,940. See paragraph bridging pages 20 and 21.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare a composition comprising BAY 38-7271 for infusion using any

suitable physiologically solution for administration as taught by Mauler. One of ordinary skill would use a vehicle known to be used for other similar therapeutic compounds, such as the aqueous solution comprising a cyclodextrin, with a reasonable expectation of success. In the absence of unexpected results, it would be further obvious to modify this composition by adjusting it to a suitable pH for cerebral infusion with a citrate buffer with a reasonable expectation of success.

The instant claims recite a composition comprising compound I and various standard physiological excipients. However, the examiner does not find there to be any evidence of criticality in any particular mix of components.

Claims 1-4 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mauler et al (J. Pharmacol. Exp. Ther., 2002) in view of Szabo et al (J. Pharmacol. Exp. Ther., 2001) and Yamada (US 5,807,337).

Mauler and Szabo teach as set forth above. The references teach the infusion of cannabinoid receptor agonists but are silent regarding the description of the infusion apparatus used in each reference.

It is well known in the art to use an infusion apparatus for the continuous administration of therapeutic agents, and the drug-contacting surfaces are typically plastic. See, for example, Yamada at col 5, lines 15-25.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare the recited composition, as set forth above. It would be further obvious to combine the composition with an infusion apparatus to form a kit for administration

of the composition. It would be within the scope of the artisan to select any appropriate apparatus for this utility.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Monday, Wednesday and Thursday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang at (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

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Leigh C. Maier

Leigh C. Maier
Primary Examiner
September 24, 2007